UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327** **Mem**
THIS DOCUMENT RELATES TO: WAVE 1 CASES IDENTIFIED IN EXHIBIT A TO DEFENDANTS' MOTION	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN OPINIONS OF MICHAEL THOMAS MARGOLIS, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants") submit this reply memorandum in further support of their motion to exclude certain opinions of Michael Thomas Margolis, M.D.

INTRODUCTION AND SUMMARY

Perhaps for the first time in mesh litigation, Plaintiffs expressly concede in their opposition brief that Dr. Margolis is not a biomaterials expert. Yet, Plaintiffs also argue that this lack of expertise should not limit his proposed testimony – which includes biomaterial analysis. Plaintiffs cannot have it both ways; Dr. Margolis should be prohibited from offering opinions regarding biomaterial properties of mesh. Moreover, certain opinions he offers regarding Defendants' knowledge and labeling inadequacies also require more than the clinical expertise he admittedly possesses, despite Plaintiffs' arguments to the contrary. Finally, as detailed below, Dr. Margolis's methodology in support of his design defect theories remains flawed, rendering his opinions unreliable and inadmissible.

LEGAL ARGUMENT

I. Plaintiffs admit Dr. Margolis lacks biomaterial expertise, and this deficit necessarily impacts the scope of his testimony.

Biomaterial is defined as "a natural or synthetic material (as a metal or polymer) that is suitable for introduction into living tissue especially as part of a medical device (as an artificial joint)." http://www.merriam-webster.com/medical/biomaterial. Biocompatability is defined as "the condition of being compatible with living tissue or a living system by not being toxic or injurious and not causing immunological rejection." http://www.merriam-webster.com/medical/biocompatibility. Thus, biomaterial expertise would require special skill and knowledge regarding the suitability of a material for use with living tissue, including whether it was toxic or injurious, or caused immunological rejection. In the present case, such knowledge would include expertise sufficient to formulate opinions regarding whether polyurethane mesh is "suitable" for introduction into living vaginal tissue, and explain why or why not.

Plaintiffs admit that Dr. Margolis is *not* a biomaterials expert. Plaintiffs' Opposition Brief (Pltfs' Opp.) at 16. Nonetheless, Dr. Margolis offers detailed opinions regarding the suitability of mesh for use in the living tissue of the vagina, and opines regarding his beliefs as to why it is not compatible – including its alleged propensity to degrade due to the chemical composition of Prolene, particle loss due to the design cutting technique, inflammation due to foreign body reaction caused by the material composition, and improper integration with living tissue due to pore size and weight. The Court should preclude Dr. Margolis from rendering opinions on these biomaterial characteristics. Dr. Margolis's reports touch upon all of these topics, and opine on the way in which a synthetic material interacts with living tissues—*i.e.*, the subject of biomaterials science.

As in other cases, Plaintiffs have not offered any additional evidence in opposition to Defendants' argument that Dr. Margolis is not qualified to opine on these topics. *See Mathison v. Bos. Sci. Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *9-10 (S.D. W. Va. May 6, 2015) (noting that plaintiffs avoided a substantive response to biomaterials expertise challenge, engaging in "intentional ambiguity", resulting in the MDL court excluding Dr. Margolis's testimony on biomaterials and biocompatibility, among other topics); *see also Winebarger v. Bos. Sci. Corp.*, 2015 WL 1887222, at *11 (S.D. W. Va. Apr. 24, 2015) (same). They simply repeat the mantra that he has performed thousands of surgeries and is a qualified pelvic surgeon. Expertise in how to remove and implant medical devices is decidedly different than expertise in *why* those devices are (or are not) biocompatible. Accordingly, although Dr. Margolis may be qualified to testify about the complications he has actually seen when removing mesh, such as scarring or roping, he is not qualified to testify as to what biomaterial properties of polypropylene mesh he believes *cause* such scarring or roping or how the material and chemical reactions result in bio-incompatibility. Similarly, while this Court has held in other cases that Dr. Margolis may comment on the effectiveness of the TVT, that should not include the ability to offer opinions regarding the biomaterial properties of mesh that he believes causes it to be ineffective.

For these reasons, Dr. Margolis' lack of biomaterials expertise precludes him from testifying about the biomechanical properties of mesh, including theories regarding its biocompatibility (or lack thereof).

II. Defendants have objected to specifically identified statements that constitute inadmissible state-of-mind opinion testimony.

In their memorandum in support of their motion to exclude, Defendants set forth specific examples of proposed testimony that impermissibly addresses Defendants' state of mind and

knowledge. Memorandum in Support of Motion at 3-4. In other cases, this Court has declined to "parse the numerous reports and thousand-page depositions" to determine the validity of such objections. In the present case, however, Plaintiffs argue that the specific statements identified in Defendants' opening memorandum are not impermissible and Plaintiffs reaffirm their intent to offer the testimony at trial. Pltfs' Opp. at 5.

There is nothing about Dr. Margolis's training and experience as a pelvic surgeon that affords him special expertise or clairvoyance that would somehow enable him to testify about Defendants' state of mind. Moreover, to the extent that Dr. Margolis's proposed statements simply regurgitate facts from corporate documents, these concern mere "lay matters which a jury is capable of understanding and deciding without the expert's help." *Andrews v. Metro N. Commuter R.R. Co.*, 882 F.2d 705, 708 (2d Cir. 1989).

Because Plaintiffs have indicated that they contest that inadmissibility of the identified statements, the issue is ripe for decision.

III. Dr. Margolis's opinions related to product warnings go beyond his clinical expertise.

Plaintiffs concede that Dr. Margolis is not an expert on regulatory requirements of medical device warnings and that he will not opine as to whether the TVT and TVT-O labeling conformed to FDA requirements. Pltfs' Opp. at 7. They nevertheless defend his ability to testify "about the risks he perceives (as a pelvic surgeon) from the devices and whether the IFUs for devices adequately conveys those risks." However, the many labeling criticisms Dr. Margolis offers go beyond his clinical perspective into legal and regulatory territory. He opines not only about the IFU's inadequate disclosure regarding "risks he perceives," such as dyspareunia and erosion, but also about alleged inadequate disclosures regarding pre-marketing studies, biomaterial mechanisms underlying the resulting "risks," as well as the lack of severity and

frequency rates (despite the fact that Dr. Margolis provides no basis for requiring Ethicon to disclose such rates other than his own preferences).

For instance, Dr. Margolis opines that Ethicon did not adequately study the product and should have included "severity and frequency" rates of alleged complications in the IFU. (TVT Rep. at 21-23)(attached as exhibit D to motion). These criticisms go beyond his clinical experience. Unlike opining that the label did not disclose a particular potential complication that Dr. Margolis has perceived in practice, these criticisms are directed at Ethicon's pre- and post-marketing trials and studies, which involve marketing and regulatory expertise that Dr. Margolis does not have. Likewise, his opinion that frequency and severity rates for potential complications should be disclosed for the warnings to be adequate invokes regulatory and legal expertise – and he again offers no basis for these opinions other than his own preferences.

Similarly, he criticizes Ethicon's alleged failure to warn of "fibrotic bridging", "inadequate pore size" and degradation, which are biomaterial reactions and properties that allegedly cause the symptoms he encounters. (TVT Report at 13, 19-20; *see also* TVT-O Report at 13). The clinical symptoms he associates with fibrotic bridging and degradation, such as pain and erosion, are what Dr. Margolis treats and observes in his clinical practice – and those are clinical symptoms to which his testimony should be limited. Yet, Dr. Margolis goes beyond testifying as to the complications that he perceives and instead, as Plaintiffs themselves note, he describes in detail the "relationship between the degradation of mesh and chronic foreign body response," Pltfs' Opp. at 12, which falls squarely in the biomaterial compatibility arena.

Accordingly, while this Court has held in other cases that urogynecologists like Dr. Margolis may testify about the risks that they perceive and then opine that the IFU did not convey those risks, that should not include opining about the failure to conduct studies or to

disclose biomaterial compatibility properties (such as particle loss, degradation and fibrotic bridging) that may (or may not) have the ability to cause the symptoms he sees and treats in practice.

The Court should preclude Dr. Margolis from testifying about product warnings that are not founded upon his clinical observations as a surgeon, because it is outside his area of expertise.

Moreover, as to certain "complications" Dr. Margolis identifies, see pages 7-8 of Dr. Margolis's reports, he has not provided evidence reliably attributing the complications to TVT. *See, e.g.*, Margolis *Batiste* (11/26/13) Dep. 205:12-207:3 (attached as exhibit F to motion)(failing to identify any studies showing that TVT was capable of clinically significant degradation). For example, Dr. Margolis criticizes Defendants' mechanically cut mesh (MCM) as inferior to laser-cut mesh (LCM), in that LCM allegedly experiences less particle loss than MCM. (TVT Rep. at 16-18; TVT-O Rep. at 16-18). He initially testified that "eroded mesh particles" could be found in other parts of the body, but subsequently admitted they could not be found anywhere except the vaginal canal. (Margolis *Batiste* (11/26/13) Dep. 206:9-22). He also admitted he had no clinical literature supporting his theory that degraded polypropylene mesh particles increase the inflammatory response. (Margolis *Batiste* (11/26/13) Dep. 206:23-207:3). Because Dr. Margolis can cite no reliable bases for these theories, these opinions should be excluded under *Daubert* and Rule 702 for lack of "sufficient underlying facts or data." Fed. R. Evid. 702.

IV. The Court should exclude Dr. Margolis's opinions related to Prolene mesh's alleged unsuitability for implantation in the vagina.

Dr. Margolis should not be permitted to opine that Prolene mesh is not suitable for implantation in the vagina. Ex. C to Motion, TVT-O Rep. at 11. That type of biomaterial compatibility conclusion should be firmly grounded in established biomaterial expertise – which

Dr. Margolis and Plaintiffs have admitted he does not have. Plaintiffs only rebuttal on this issue is that his opinion is consistent with testimony he gave to the FDA and is allegedly consistent with the Material Safety Data Sheets accompanying the unprocessed polypropylene manufactured by Phillips Sumika and Chevron Corporation. Pltfs' Opp. at 15-16. Yet, the fact that Dr. Margolis has offered this same opinion before does absolutely nothing to establish its reliability. Rather, it is a prime example of impermissible *ipse dixit:* he himself said it (twice); therefore, it must be so. This hardly rises to the level of reliability required by *Daubert*. Similarly, information related to unprocessed polypropylene prepared by other companies, on Material Data Sheets that Dr. Margolis does not use or see in his clinical practice, provide insufficient support for the conclusion that treated and processed Prolene is not suitable for implantation in the vagina.

Dr. Margolis's broad statements suggesting that TVT is ineffective and that TVT should be pulled from the market, (s*ee, e.g.*, Margolis *Batiste* (11/26/13) Dep. 82:16-23, 91:18-92:2, 116:9-118:21, 128:25-129:16) are equally unreliable. When asked if he could "point to a study that says that the TVT is not effective" or any "peer reviewed published literature that says TVT has low success rates," Dr. Margolis was unable to do so. (Margolis *Batiste* (11/26/13) Dep. 128:25-129:16). Plaintiffs have failed to shore up these statements. These opinions have no scientific basis, and certainly not a basis that passes *Daubert* scrutiny.

V. Dr. Margolis offers no reliable basis for claims that the Burch procedure is more effective, has fewer complications or is less painful.

As set forth in Defendants' Memorandum in support of their Motion, Dr. Margolis has not identified any reliable basis for his claims that the Burch sling is more effective, has fewer complications or is less painful. Plaintiffs do not directly address this argument in their opposition. In passing, Plaintiffs reference one text that mentions one prospective randomized

trial of ninety patients whose cure rates following a Burch procedure ranged between 93% and 88%. Pltfs' Opp. at 15, citing John A. Rock, M.D. & Howard W. Jones III, M.D., Te Linde's Operative Gynecology (10th ed. 2011) (attached as exhibit D to Plaintiffs' Opp.). That text also states, on the same page, that cure rates for the traditional Burch and MMK procedures range from 85% to 90% at 1 to 5 years, and 70% at 10 years. Six pages later, the text describes tension free polypropylene mesh sling cure rates of 85% at "long term follow-up." *Id.* at 945. On the same page, the text describes "tension-free midurethral sling" as "an effective, minimally invasive technique". *Id.* This article is insufficient to support Dr. Margolis's opinions regarding superior Burch procedure cure rates and efficacy, and actually undercuts his opinion that TVT mesh is ineffective and unsuitable for treatment of SUI.

This Court has routinely excluded opinions regarding complication rates and general effectiveness where plaintiffs, as here, fail to provide sufficient scientific support for such generalized statements. *See Mathison*, 2015 WL 2124991, *7-8 (excluding opinions of Dr. Margolis regarding failure rates where he failed to explain why he disagreed with contrary studies and discounted scientific studies and instead gave patients "the benefit of the doubt" as to complication rates); *Trevino v. Boston Sci. Corp.*, No. 2:13-CV-01617, 2016 WL 1718836, at *8 (S.D.W. Va. Apr. 28, 2016)(excluding Dr. Margolis's opinion where he failed to provide a scientific basis for disagreeing with studies that find lower pain rates in women with polypropylene mesh and slings). Moreover, as this Court has recently observed, Dr. Margolis "may not rely on his personal observation when he seeks to provide broad opinions . . ." such as these. *Trevino*, 2016 WL 17178836 at *9. Because Plaintiffs here have not identified a sound scientific basis for these opinions, the same conclusion should be reached in this case.

VI. Dr. Margolis's analogies are impermissibly inflammatory, with any probative value outweighed by the potential for prejudice.

Contrary to Plaintiffs' suggestion, Defendants have not argued that metaphors are generally impermissible; indeed, appropriate analogies, supported by factual evidence can be helpful to a jury. Dr. Margolis, however, routinely employs extreme hyperbole in order to shock the audience rather than to genuinely aid in understanding. Determining admissibility requires comparison of the probative value and prejudicial or inflammatory aspects of the testimony. Plaintiffs' attempts to defend this hyperbole are utterly unconvincing.

First, Plaintiffs try to explain that the Mount Krakatoa analogy refers to mesh, not to the patient's vagina, and thus is somehow more appropriate. Clearly it's a distinction with no substantive difference. If the mesh is erupting like a volcano (which it is not), then it is erupting through vaginal tissue that, in Dr. Margolis's analogy, would act as the walls of the volcano. However, the real issue that the court must address is whether this analogy, and others like it, are calculated to inflame more than inform. The facts in evidence do not support the analogy of mesh to an erupting volcano that kills thousands of people. Mesh does not explode, it does not spew smoke and ash (or any other toxin) throughout the surrounding area, and it is not even alleged to be capable of causing death. Accordingly, the analogy is not helpful to understanding mesh, and it is calculated to shock and inflame the jury prejudicing Defendants. The concept of a recurring injury that may lie dormant for periods of time is not complex and can be explained without comparing a woman's vaginal mesh to a notorious volcano responsible for the deaths of tens of thousands of innocent people. In the present case, any probative value is outweighed by the inflammatory comparison.

Similarly flawed are Dr. Margolis's analogies to shattered glass and rebar. Unlike a shattered glass accidentally dropped on the floor, mesh is intended to be implanted in the body and is intended to incorporate itself into the tissue. As previously discussed, Dr. Margolis offers

no evidence that mesh particles migrate anywhere else in the body. The analogy is unfair and unsupported by evidence. It is therefore prejudicial.

While facially appealing, the rebar analogy fairs no better. Although mesh is designed to reinforce tissue, living tissue is not the same as inert concrete. Living tissue can be manipulated with a scalpel, and the scientific literature reports many exposures treated easily with excision or revision. In contrast, rebar is inflexible and smaller parts cannot be excised without disturbing the whole. Whatever potential value such analogy might have had is overwhelmed by its inflammatory phrasing, lack of support and development.

The *Astrazeneca LP v. Mylan Pharmaceuticals, Inc.* case cited by Plaintiffs in support of their counter-argument is inapposite. 2011 WL 2516381 (D. Del. June 23, 2011). First, the court in that case was not asked to determine the admissibility of testimony that would be presented to a jury, so the court never weighed the probative value versus the inflammatory nature of the analogies offered. Instead, the analogies occurred in a bench trial and were later "mocked" by the defendant in post-trial briefing. *Id.* at n.8. In that unique context, the court acknowledged in passing, in a footnote, that both parties' experts had made use of analogies, but took issue with the defendant's briefing that "mocked" plaintiff's expert's testimony analogizing the product to pasta, which swells when overcooked. In a footnote, the court called out the "condescending tone" of the briefing, noting that the defendant's sarcasm was particularly ironic because the defendant's expert had already used a more inflammatory analogy by comparing one of the chemicals in the product to a "little time bomb." *Id.* at 5 n.8. Federal Rule of Evidence 403 was never considered.

Dr. Margolis's extreme descriptions and overstatements have little to no probative value and would only unfairly prejudice Defendants in this trial. Accordingly, Defendants move this Court to preclude any such hyperbole by Dr. Margolis.

CONCLUSION

For the reasons set forth above, the Court should limit the parameters of Dr. Margolis's testimony consistent with the foregoing.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on May 16, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
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